

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,

Plaintiff,

v.

AMERISOURCEBERGEN CORPORATION,
et al.,

Defendants.

CIVIL ACTION
NO. 22-5209

January 31, 2025

MEMORANDUM

AmerisourceBergen Corporation¹ moved to compel production of documents pursuant to eight specific document production requests. The Government has agreed to produce several categories of documents covered by these requests but refuses to produce purely internal communications and documents reflecting DEA personnel's views of the law. The Court denies Amerisource's motion because internal communications reflecting the unofficial views of DEA personnel are not relevant.

I

A

The Court detailed this case's factual background in a prior Opinion. *See United States v. Amerisource Bergen Corp.*, No. 22-5209, 2023 WL 7311183 (E.D. Pa. Nov. 6, 2023) (ECF No. 47.) At its core, the United States alleges Amerisource violated the Controlled Substances Act by failing to report suspicious orders to the DEA. The CSA

¹ After the Government filed this lawsuit, AmerisourceBergen Corporation changed its name to Cencora, Inc. (Notice of Corporate Name Change at 1, ECF No. 46.) Defendants AmerisourceBergen Drug Corporation and Integrated Commercialization Solutions, LLC's names remain the same. The Court refers to the defendants collectively as Amerisource.

requires each registrant² to “design and operate a system to identify suspicious orders” and, “upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.” 21 U.S.C. § 832(a)(1), (3). The Government seeks civil penalties for each alleged violation.

The parties previously wrote the Court previewing to an extent their current disagreements. (Amerisource Discovery Letter pp. 1-2, ECF No. 80); (Government Discovery Letter p. 1, ECF No. 81.) The issues were presented very generally and not tailored to specific documents so the Court asked the parties to continue their efforts to resolve their differences and file the appropriate motion if those efforts failed. (Aug. 7, 2024 Memo. Op. at 2, ECF No. 82.) Amerisource has now filed such a motion, (Mot. to Compel, ECF No. 83), to which the Government responded, (Brief in Opp. to Mot. to Compel, ECF No. 85.)

B

Amerisource identifies suspicious orders through a two-step process: first, prescription drug orders that exceed certain statistical thresholds are flagged by its computer algorithm as “orders of interest”; second, orders of interest are reviewed by human analysts and either confirmed as suspicious or cleared of suspicion. (Brief in Supp. of Mot. to Compel at 2.) At the heart of this dispute is whether orders of interest

² A registrant is “any person who is registered pursuant to either” 21 U.S.C. §§ 823 or 958. 21 C.F.R. 1300.01(b).

“flagged by [Amerisource’s] algorithms unquestionably met the statutory and regulatory meaning of suspicious.” (Compl. ¶ 212, ECF No. 1.)

Amerisource’s eight requests seek three broad categories of documents:

- (1) Purely internal DEA communications and documents reflecting (A) agency personnel’s interpretation of “suspicious order,” (B) how that definition applies to orders of interest and the impact of the *Masters* D.C. Circuit decision,³ and (C) deliberations and documents relating to a 2020 notice of proposed rulemaking on the definition of suspicious order;
- (2) DEA communications with relevant third parties describing the industry’s reporting obligations, including whether to report orders of interest, and documents reflecting such communications; and
- (3) DEA communications with and about Amerisource describing its reporting obligations, including whether it was required to report orders of interest, and documents reflecting such communications.

(Brief in Supp. of Mot. to Compel at 4-5.) The Government has agreed to produce “correspondence between DEA and external parties regarding the interpretation of the suspicious order reporting laws,” (U.S. Sept. 20, 2024 Letter at 3, ECF No. 83-4), “internal DEA documents reflecting the contents of communications between DEA and external parties regarding the same,” (*id.*), and “DEA communications regarding the application of the suspicious order reporting laws to the conduct at issue in this case—in particular, communications regarding the application of those laws to Defendants’ suspicious order monitoring and reporting practices,” (*id.* at 4); *see also* (Brief in Opp. to Mot. to Compel.)⁴ The Government has thus agreed to produce documents falling into

³ *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

⁴ The Government has also expressed a willingness to produce “internal communications from the custodial files of non-attorney DEA personnel whom Defendants contend provided them with direct and specific advice . . . regarding the interpretation of suspicious order reporting laws that Defendants contend is inconsistent with the Government’s legal theory in the Complaint.” (*Id.* at 4 n.4.) It claims Amerisource failed to identify any such individuals.

the second and third categories, leaving the Court to resolve the disagreement over the first.

II

Under Federal Rule of Civil Procedure 26, parties may obtain discovery regarding any nonprivileged matter relevant to any party's claim or defense and proportional to the needs of the case. Fed. R. Civ. P. 26(b)(1). Proportionality depends on several factors, including "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Id.*

The party moving to compel discovery "bears the initial burden of proving the relevance of the requested information." *Houser v. Wetzel*, No. 24-603, 2024 WL 1913162, at *4 (M.D. Pa. May 1, 2024) (citing *Morrison v. Phila. Hous. Auth.*, 203 F.R.D. 195, 196 (E.D. Pa. 2001)). If that burden is satisfied, "the party resisting the discovery has the burden to establish the lack of relevance by demonstrating that the requested discovery (1) does not come within the broad scope of relevance as defined under Fed. R. Civ. P. 26(b)(1), or (2) is of such marginal relevance that the potential harm occasioned by discovery would outweigh the ordinary presumption in favor of broad disclosure." *Id.* (quoting *In re Urethane Antitrust Litig.*, 261 F.R.D. 570, 573 (D. Kan. 2009)).

III

A

Amerisource claims the internal DEA documents are relevant to the reasonableness of its conduct. To be liable for failure to report suspicious orders, a defendant must have been negligent. 21 U.S.C. § 842(a)(5). The statute does not define negligence, but other courts have applied the word's ordinary meaning; that is, "the failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation." *United States v. Greene*, No. 17-cv-272, 2019 WL 6050213, at *4 (N.D. Ga. Nov. 15, 2019); *see also* Negligence, Black's Law Dictionary (7th ed. 1999). Amerisource contends internal DEA documents reflecting agency personnel's private legal interpretations are relevant to what a reasonably prudent registrant would have done in similar circumstances.

As a preliminary matter, direct communications between DEA personnel and industry stakeholders regarding their reporting obligations are likely relevant to the reasonableness inquiry, and the DEA has agreed to produce all such communications. *See generally* (U.S. Sept. 20, 2024 Letter). The relevance of DEA personnel's purely private views on the industry's reporting obligations, however, is a different matter. To start, lower-level personnel at the DEA are not themselves registrants, so their private views are not *per se* relevant to what a reasonably prudent registrant should do in similar circumstances. If such personnel have not communicated these views to registrants, they are irrelevant to the reasonableness of a registrant's conduct. *See United States v. Farley*, 11 F.3d 1385, 1391 (7th Cir. 1993) (noting that purely internal agency documents are "irrelevant to the central issue of this defense--determining

whether Farley should, after reading the regulations, have understood that his purchases did not fall within the definition of the investment-only exemption set out therein”); *United States ex rel. Heath v. Wis. Bell*, No. 08-C-0876, 2020 WL 13048895, at *2 (E.D. Wis. Oct. 29, 2020) (“Internal agency communications and internal agency interpretations of a rule cannot be relevant to whether the defendant knowingly violated the rule unless the defendant was aware of those internal communications and interpretations at the time the rule was violated.”); *FTC v. Amazon, Inc.*, No. 23-cv-00932, 2024 WL 3924583, at *4 (W.D. Wash. Aug. 22, 2024) (“The FTC has already agreed to produce all documents communicating its interpretations to third parties. But the FTC’s internal interpretations of ROSCA . . . has no bearing on the objective reasonableness of Defendants’ interpretation of ROSCA.”).⁵

Amerisource relies on three cases in support of its argument that internal agency documents are relevant to the reasonableness of its conduct. First, it cites *SEC v. McDermott*, No. 19-4229, 2022 WL 2337312, at *11-12 (E.D. Pa. June 24, 2022), in which the court held that “evidence of the [Security and Exchange] Commission’s internal correspondence regarding its examination of [the defendants] is admissible.” But that holding pertained to the SEC’s internal communications regarding its investigation of *the defendants*, which the DEA here has already agreed to produce. *See* (U.S. Sept. 20, 2024 Letter at 4). Amerisource also cites to *United States v. American*

⁵ Amerisource attempts to draw a distinction between the negligence standard in 21 U.S.C. § 842(a)(5) and the knowing or intentional standards at issue in some of the case law. But even under a negligence standard, reasonableness turns on the information registrants had available to them when making their decision. *See, e.g., FTC v. Amazon, Inc.*, 2024 WL 3924583, at *3 (denying an argument nearly identical to Amerisource’s where the level of scienter was whether “a reasonable person under the circumstances would have known of the existence of the provision and that the action charged violated that provision”).

Electric Power & Service Corp., No. 99-1182, 2001 U.S. Dist. LEXIS 18722, at *10 (S.D. Oh. Aug. 8, 2001), where the court noted that defendants were “entitled to conduct discovery with respect to” EPA’s interpretation of the relevant regulation. But that case addresses the weight to be afforded official agency interpretations before *Loper Bright*, not a motion to compel production of unofficial agency communications. Finally, Amerisource points to *United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, No. 16-8697, 2018 WL 8459926, at *11 (C.D. Cal. Dec. 14, 2018), where the court allowed discovery of “any documents showing that CMS’s [legal] interpretations . . . mirrored United’s own.” (quotations omitted). But the *Poehling* court “provided no additional reasoning as to why the internal agency documents were relevant.” *FTC v. Amazon.com, Inc.*, 2024 WL 3924583, at *4.

B

Requiring production of internal, deliberative agency communications poses other dangers. For example, the Court would risk elevating the unofficial, unexpressed and pre-decisional views of agency personnel to official agency pronouncements. *Farley*, 11 F.3d at 1391 (“The views of agency employees contained in intra-agency documents are not, however, expressions of FTC policy. Rather they are part of the exchange of ideas—the give and take—central to the formulation of such policy.”); *Consumer Fin. Prot. Bureau v. Navient Corp.*, No. 17-CV-101, 2018 WL 2088760, at *4 (M.D. Pa. May 5, 2018) (“What agency staff said in communication leading up to the issuance or non-issuance of rules, policies, or guidance has no bearing on that determination. If it were otherwise, these predecisional communications would possess de-facto official status.”); *FTC v. Amazon, Inc.*, 2024 WL 3924583, at *3 (“Internal

agency interpretations of a statute have no legal significance because they are not official agency positions.”) (citing *Navient*).

Such discovery could also have a chilling effect on agency policymaking deliberations, a concern underlying the deliberative process privilege.⁶ *Farley*, 11 F.3d at 1389 (“Since frank discussion of legal and policy matters is essential to the decisionmaking process of a governmental agency, communications made prior to and as a part of an agency determination are protected from disclosure.”); *see also generally* 5 U.S.C. § 552(b)(5) (exempting agency draft reports and internal communications from disclosure under the Freedom of Information Act). Absent a more compelling relevance argument, the “potential harm occasioned by discovery” of these documents far outweighs “the ordinary presumption in favor of broad disclosure.” *Houser*, 2024 WL 1913162, at *4.⁷

⁶ The government argues that the internal agency documents are “likely protected by” the deliberative process privilege. Under Federal Rule of Civil Procedure 26(b)(5)(A), the party asserting a privilege must expressly make the claim and describe the nature of the allegedly privileged materials in a way that enables other parties to assess the claim.

Courts have required other procedural requirements to be met before a party can invoke the privilege. *See Three Brothers Supermarket Inc. v. United States*, No. 19-2003, 2020 WL 5231575, at *2 (E.D. Pa. Sept. 1, 2020) (explaining the procedural requirements for invoking the deliberative process privilege, including the head of the department with control over the matter making a formal claim of privilege, supported by an affidavit, which gives precise reasons for the confidentiality of the communications).

Here, the Government offers little more than a “broad invocation of the privilege by government attorneys in a legal brief.” *Id.*

⁷ To the extent Amerisource wants these documents to show that DEA personnel themselves disagreed with the Government’s current legal theory, statutory interpretation is a job for the Court. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024). The private views of DEA personnel regarding “suspicious order” reporting obligations is owed no deference by the Court in fulfilling its obligation to say what the law is. *See, e.g., FTC v. Amazon, Inc.*, 2024 WL 3924583, at *3; *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (“The non-public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant.”).

C

Amerisource argues that internal agency communications are also relevant to: (1) potential penalty assessments, (2) its affirmative defenses of estoppel and acquiescence, and (3) impeachment of government witnesses. (Brief in Supp. of Mot. to Compel at 9.)

The statute contemplates a maximum fine of \$100,000 for each violation of suspicious order reporting requirements. 21 U.S.C. § 842(c)(1)(B)(ii). “In determining the fine to be imposed, the court should consider (1) the willfulness of the violations; (2) whether, and to what extent the defendant profited from the illegal activity; (3) harm to the public; and (4) the financial capacity of the defendant to pay.” *United States v. Queen Village Pharmacy*, No. 89-2778, 1990 WL 165907, at *2 (E.D. Pa. Oct. 25, 1990). Amerisource believes internal agency communications are relevant to the first factor, “Defendants’ alleged culpability,” (Brief in Supp. of Mot. to Compel at 9), but that argument is untenable for the same reasons given above. Amerisource also claims the documents are relevant to public harm because “DEA did not actually expect or tell Defendants to report.” (*Id.*) But whether DEA expected Amerisource to report is irrelevant to the level of harm Amerisource’s conduct caused to the public.

Amerisource next cites its estoppel and acquiescence defenses, claiming internal DEA documents are relevant to demonstrating “Defendants’ reasonable reliance on DEA statements.” (*Id.*) The Government has already agreed to produce all communications it made to Amerisource and other registrants. Amerisource does not explain how it could have relied on private statements it was never privy to.

Finally, Amerisource believes the internal agency documents are relevant to the impeachment of government witnesses, specifically former DEA employee Demetra Ashley. But Amerisource does not describe what Ashley's testimony may be and how *all* internal DEA communications, or even just those involving her, would be relevant to her impeachment. Amerisource has not met its burden to have the Court compel production on these grounds.

An appropriate Order follows.

BY THE COURT:

/s/ Gerald J. Pappert

Gerald J. Pappert, J.